

K093207

510(k) Summary

Summary of 510(k) Safety and Effectiveness

Submitted By: Lucero Medical, LLC.
PO Box 67
Richfield, OH 44286

APR 26 2010

Date: April 22, 2010

Contact Person: Jennifer Palinchik
Project Manager

Contact Telephone: (440) 808-9995

Device Trade Name: ENDURAMESH
Device Classification Name: Spinal intervertebral body fixation orthosis
Device Classification: Class II
Reviewing Panel: Orthopedic/87
Regulation Number: 888.3060
Product Code: MQP
Predicate Devices: DePuy Harms Mesh Cage (K003043)

Device Description:

The ENDURAMESH is a vertebral body replacement system which provides structural support of the vertebral bodies following an anterior or far lateral corpectomy, aiding in spinal fusion. The device may be used with a cleared supplemental fixation system based on surgeon discretion and preference.

The ENDURAMESH vertebral body replacement system consists of a single cylindrically shaped titanium mesh cage. The hollow core of the cage allows for packing bone graft and the circular holes throughout the device promote bone fusions. Various diameters and heights are available to accommodate variability among patients.

Indications for Use:

The ENDURAMESH is a vertebral body replacement system intended for use in the thoracic and lumbar spine (T1-S1) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma/fracture. The device is intended for use with either allograft or autograft. The device may be used with a cleared supplemental fixation system based on surgeon discretion and preference.

Substantial Equivalence Information:

The design features, material, and indications for use of the ENDURAMESH system are substantially equivalent to the predicate devices listed above. The safety and effectiveness is adequately supported by the substantial equivalence, material information, and analysis data provided within this Premarket Notification.

Summary of Non-Clinical Tests:

The following mechanical testing was performed per ASTM F2077 and ASTM F2267 to demonstrate substantial equivalence of the subject device to the predicate device: Static Compression, Dynamic Compression, Static Torsion, Dynamic Torsion, Subsidence, and Expulsion. The device functioned as intended and the performance results show that the ENDURAMESH is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APR 26 2010

Lucero Medical, LLC
% Ms. Jennifer Palinchik
Project Manager
P.O. Box 67
Richfield, Ohio 44286

Re: K093207

Trade/Device Name: Enduramesh
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: April 12, 2010
Received: April 16, 2010

Dear Ms. Palinchik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093207

Device Name: ENDURAMESH

Indications for Use:

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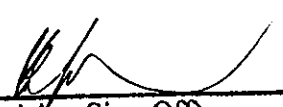
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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